K043397
1 of 2

DEC 2 9 2004

510K SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitted By:**

Pasquale Amato
Regulatory Affairs Coordinator

BD Medical Surgical Systems
1 Becton Drive
Franklin Lakes, NJ 07417

Phone: 201-847-4513
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2. **Device Name:**

Trade Name: BD Eclipse™ Hypodermic Needle

Common Names: Eclipse Hypodermic Needle

Classification Name: Needle, Hypodermic, Single Lumen

3. **Predicate Device:**

BD Eclipse™ Hypodermic Needle

Manufactured by: Becton Dickinson and Company

4. **Device Description:**

The BD Eclipse™ Hypodermic Needle (BD Eclipse™ Hypodermic Needle 510(k): K010188) is a device that is composed of a typical hypodermic needle with a one-piece hub/adapter and pivoting cover that is connected to the adapter. The hub of the modified device has a metal clip assembled in it to ensure that the BD Eclipse™ Hypodermic Needle is attached to a luer slip syringe with sufficient force by the user. The pivoting cover can be manually rotated forward after use allowing for secure encapsulation of the needlepoint making the product safe for disposal.

The basic needle dimensions (diameter, injection length, needle tip geometry, materials and lubrication) are the same for the BD Eclipse™ Hypodermic Needle, modified device, the standard BD Hypodermic Needle and the predicate device BD Eclipse™ Hypodermic Needle.

5. **Intended Use:**

The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Hypodermic Needle is compatible for use with standard luer-slip and luer-lock syringes.

The BD Eclipse™ Hypodermic Needle contains a mechanism that covers the needle point after use. In the activated position the needle cover guards against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

6. **Technological Characteristics:**

The B-D Eclipse™ Hypodermic Needle and the predicate device have the identical technological characteristics and perform equivalently.

The only difference between the BD Eclipse™ Hypodermic Needle and the predicate device is the metal clip in the hub.

7. **Performance:**

Bench tests and Simulated Use Test relating to the performance of the BD Eclipse™ Hypodermic Needle were conducted.

The results of these tests demonstrate that the BD Eclipse™ Hypodermic Needle perform equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 9 2004

Mr. Pasquale Amato
Regulatory Affairs Coordinator
Becton Dickinson & Company
BD Medical Surgical Systems
1 Becton Drive
Franklin Lakes, New Jersey 07417

Re: K043397
Trade/Device Name: BD Eclipse™ Hypodermic Needle
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 8, 2004
Received: December 10, 2004

Dear Mr. Amato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043397

Device Name: BD Eclipse™ Hypodermic Needle

Indications For Use:

The BD Eclipse™ Hypodermic Needle is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Eclipse™ Hypodermic Needle is compatible for use with standard luer-slip and luer-lock syringes.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anne Naveau for ADW 12/29/04
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K043397